REMARKS

Claims 49-65 are pending in this application. New independent claim 65 has been added to further clarify that which the Applicants' regard as their invention.

Claims 49-64 were previously rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

Contrary to the statement in the previous Office Action, the last paragraph of page 8 does not indicate that "it is practiced with 'normal' lymphocytes" in the restrictive sense meant by the Examiner. The specification actually states that the method "involves collecting blood from the ill individual and growing the normal lymphocytes in culture, harvesting the propagated cells, ..." A proper reading of this statement is that "the normal lymphocytes" in the blood sample are "the propagated cells" that are harvested. This is the specific procedure described at pages 8-10 of the specification. The procedure described at page 8-10 does not include any specific step to separate "normal" from any "abnormal" lymphocytes prior to propagating the lymphocytes. In fact, it states that "all lymphocyte layers [obtained from the blood sample] are combined and washed . . . " (Step 6), then "added to cell culture flasks containing [a] cell culture medium" (Step 8), and then "incubated at 37°C and monitored daily until yield is approximately 5-8 x 10^6 cells per ml (Step 10).

Furthermore, the word "normal" as used in this application does not create any ambiguity to a person of skill in the art. For example, the types of cells obtained according to the disclosed methodology for preparing an "autogenous lymphocytic factor" ("ALF") derived from a blood sample of the individual as described in the most preferred embodiment at pages 8-10 of the originally-filed specification make the meaning clear. A person of ordinary skill in the art would recognize from the disclosure in this application and background knowledge in the field that even an immunologically-challenged or otherwise sick individual would have at least some "normal" lymphocytic cells in his or her blood, and that large numbers of "normal" or "robust" lymphocytic cells can be propagated from the person's blood sample when the cells are cultured outside the person's immunologically-compromised body. Specification, page 15, lines 14-18. Under culturing conditions such as those described in the application, "normal" lymphocytic cells will propagate in favor of "unhealthy" or "dysfunctional" cells. As is well known in the art, the functionality (i.e., functional index) of cells is demonstrated by blastogenisis under culturing conditions. The method disclosed in the application is clear to a person of skill in the art.

Claims 49-59 were previously rejected under 35 U.S.C. § 103(a) as being unpatentable over Youdim et al. in view of Warren (U.S. Patent No. 4,435,384). This rejection is respectfully traversed, for the following reasons.

Youdim et al. does not disclose that its transfer factor is prepared from <u>cultured</u> leukocytes (see page 56, first column). Contrary to the statement in the previous Office Action, Warren does not teach or suggest that the cells are propagated. And contrary to the statement in the previous Office Action, Warren does not disclose any culturing of cells in vitro. The Examiner is apparently referring to Warren, at Column 2, step 5 of its method, which states: "Incubate the syringe and contents for 20 minutes at 37°C." As well known to those skilled in the art, however, and as described in the Applicant's specification at page 5, lines 13-16 and in Figure 1, the overall cell doubling time is about 20 - 24 hours. In Applicants' particular method disclosed at pages 8-10, the "culture is incubated at 37°C <u>and monitored daily</u> until yield is approximately 5-8 x 10^6 cells per ml." In contrast, "incubation" for only 20 minutes is not anywhere near enough time to propagate mammalian cells. Furthermore, Warren does not teach or suggest the use of any cell growth medium, as expressly required by Applicants' claims 52-54 and 60-64.. It is impossible for such a short "incubation" and without any cell growth medium as disclosed in Warren to be considered propagating cells within the meaning of Applicants' claims.

Also, Youdim et al. does not teach or suggest that the transfer factor was prepared from autologous blood cells as per the claimed invention. Warren does not teach or suggest that its transfer factor can be obtained from autologous blood cells as per the claimed invention. Instead, Warren teaches that the donor of the cell sample can have no history of recurrent infection by herpes virus. The very fact that Warren teaches such a limitation on the selection of the donor for the cell sample makes it plain that Warren does not contemplate that the donor can be the same as the patient, that is, it does not contemplate autologous blood cells. Although Warren does not say why, that limitation is apparently designed to protect the patient from infection by the herpes virus. Neither Youdim et al. nor Warren, separately or in combination, teach or disclose the advantage of using autogenous blood cells, including that the patient need not be exposed to risk of infectious disease from a donor, and does not offer the autogenous benefits disclosed by the application, such as less likelihood of rejection. See, e.g., the specification at page 10, lines 8-10. Therefore, the hypothetical combination of Youdim et al. and Warren would not suggest Applicants' invention as claimed..

Furthermore, the general purpose of the transfer factors disclosed in Youdim et al. and Warren is to transfer a trait from the donor to another person who may not have that trait. This is different from the purpose of treating an environmentally-sensitive patient with an autologous material (ALF) as per the claimed invention.

Reconsideration of the application is respectfully requested. Claims 49-65 are believed to be in condition for allowance, and such action is respectfully requested. If a further telephone interview would expedite the prosecution of this application, the undersigned would appreciate a call at the number below.

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